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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/329,002	06/08/1999	CHARLES R. MOONEY	ECC-5062CIP2	7619

7590

11/30/2001

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EXAMINER

THANH, LOAN H

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 11/30/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/329,002

Applicant(s)

MOONEY ET AL.

Examiner

LoAn H Thanh

Art Unit

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-- Th MAILING DATE of this communication appears on th cover sh et with th correspond nce address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11, 20-24, 26-37, 60-70 and 75-80 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 20-24, 26-37, 60-70 and 75-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 27 August 2001 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant has not argued which claim is generic and thus, the Examiner is maintaining there are no generic claims.

The requirement is still deemed proper and is therefore made FINAL.

An action on the merits now follows.

***Response to Amendment***

The drawing objection has been withdrawn in view of the proposed drawing filed 8/27/01. The drawing proposal has been approved.

The rejection under 35 USC § 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraph has been withdrawn in view of the amendment filed 8/27/01.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-7, 17, 21-24, 26-29, 30-33, 37, 60-67, 69-70, 77-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Palestrant (U.S. Patent No. 5,472,418).

Palestrant discloses an outer tube (46) See figs. 1-3, 4-9, 10-12. Palestrant specifically fig. 12 shows 2 auxiliary lumen and device lumen. The medical device being the guidewire (50). The flexible wall being 32 and 38. See col. 10.

4. Claim 1-3, 17-18, 20-24, 26,28-30, 37,60, 62, 75-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Young (U.S. Patent No. 5,451,206).

See figs. 1-3, 5-6, 7, 8, 12-16. Young discloses in fig. 8 the lumens ending at different location between the proximal and distal end of the outer tube. See fig. 3, 15, col. 14. Young teaches different materials with different durometers depending on what is required of the strength of the lumens.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 8-10, 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palestrant (U.S. Patent No. 5,472,418) in view of Nishijima et al. (U.S. Patent No. 5,092,846)

Palestrant teaches all the limitations of the claims except for the specifics of the device lumen valve. Nishijima et al. teaches a valve device in the analogous art of medical introducers. Nishijima et al. teaches a multi component valve insert as shown in figs. 4-5. It would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the teaching of Palestrant with the valve insert teaching of Nishijima et al. in order to provide any leakage of fluids from the body which would endanger the patient.

### ***Response to Arguments***

Applicant's arguments filed 8/27/01 have been fully considered but they are not persuasive. With respect to the discussion of Palestrant, the Examiner is taking the position that the intended use or functional language in the claims of a device imposes no limitation to the claim in the absence of distinguishing features. It has been held that the recitation that an element is "adapted to" or "is capable" of performing a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. In re Hutchison, 69 USPQ 138. Further, applicant's amended language is interpreted as functional. The claims are being interpreted broadly and considers Palestrant to still read on the claims. AT a particular point along its length, the tube of Palestrant has a cross sectional area which remains substantially unchanged. There is no change without any force applied within or external to the tube. If there was a device which is inserted then depending on the size of it, it may or may not cause a change in the cross section of the outer tube. Applicant appears to be arguing more broadly than claimed since there is no instrument that has been positively claimed to provide this force. Further, although Palestrant's outer tube is a collapsible Applicant is directed at figs. 3A and 11 and 12. If the tube of Palestrant was completely collapsible then the auxiliary would be closed completely along its length. That however is not the case. Collapsible and flattened does not entirely translate to being closed or

to the extreme of the situation since it would not be functional to insert if that were the case. It still is capable of meeting the structural limitations depending on the force that is applied whether it is an instrument or fluid which is causing the force. Further a cross-section is taking at one point in time and not as a something is moving to cause it to change. If any force is exerted to the exterior of applicant's invention, it would be collapsible.

As to the discussion of Young, "flexible" is a relative term. Although Young discloses that it reduces the likelihood of deflection it does not teach complete reduction. Applicant appears to be arguing the intended use of the device and not the structural limitations which is given patentable weight to an apparatus claim.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H Thanh whose telephone number is 703-305-0038. The examiner can normally be reached on 5:30 am to 3:00 pm.

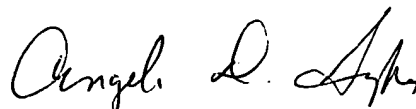
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

LT  
November 16, 2001



LoAn H Thanh  
Examiner  
Art Unit 3763



ANGELA D. SYKES  
SUPERVISORY PATENT EXAMINER  
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